management of pain associated with diabetic neuropathy from a societal perspective. **METHODS:** The study sample includes patients enrolled in the 52-week, randomized, multi-center, open-label extended phase of a duloxetine versus routine treatment trial in the management of pain associated with diabetic neuropathy. The first patient was enrolled in the study on June 14, 2001 and the last patient completed the extended phase study on April 28, 2003. A sub-population of 233 U.S. patients with diabetic neuropathic pain was randomized to either duloxetine 60 mg BID or routine pain treatment. The primary efficacy measure was the Medical Outcomes Study Short Form 36 (SF-36) bodily pain domain (BP). Total costs (direct medical and indirect productivity loss cost), adjusted to 2002 dollars using Consumer Price Index, were analyzed from a societal perspective. Bootstrap method was applied to calculate statistical inference of incremental cost-effectiveness ratio (ICER). **RESULTS:** Duloxetine treatment was associated with a significant improvement in SF-36 BP score compared with routine treatment (p-value = 0.05). From societal perspective, duloxetine is both a more cost-effective (ICER = –$429/1 BP, p = 0.04) and dominant (p = 0.06) therapy compared to routine treatment in the management of pain associated with diabetic neuropathy. **CONCLUSIONS:** This study shows that duloxetine is more cost-effective and dominant treatment for painful diabetic neuropathy compared to routine care.

DIABETES (including Parathyroid Disease)

DIABETES (including Parathyroid Disease)—Quality Of Life/Patient Preference Studies

PDB21

THE IMPACT OF COMMON DIABETIC COMPLICATIONS ON QUALITY OF LIFE

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OBJECTIVE: The microvascular and macrovascular complications of diabetes are generally associated with poorer health related quality of life, but few studies have assessed utility values associated with specific individual or multiple complications. This study estimated utilities for the most common complications, to establish whether patients have a poorer quality of life than those without complications. **METHODS:** EQ-5D index data were generated through cross-sectional postal surveys of patients on two regional registers in the UK, stratified according to the 17 most prevalent individual or multiple complications (including "none"). Amputation and blindness did not appear in this list. Subgroup analysis was undertaken on patients without chronic co-morbidities. **RESULTS:** Response rates were 62% in Brighton (n = 589) and 65% in Salford (n = 491). Nine of the most prevalent complication groups in Brighton and seven in Salford represented multiple complications. In Brighton, the lowest mean score was for patients with previous ischaemic heart disease plus peripheral vascular disease or claudication. Symptomatic neuropathy appeared in five out of the eight complication groups, which had significantly lower mean scores ($p < 0.05$) than the group without complications. Normalising for co-morbidities did not fundamentally change the findings, although mean scores were generally higher in the subgroups without co-morbidities. Stroke appeared in two, and angina in three, of the seven complication groups, which had significantly, lower mean scores ($p < 0.05$) than the group without complications. **CONCLUSIONS:** Patients with the most common diabetic complications have a poorer quality of life than those without complications. Understanding the interaction of different complications on patients' quality of life will be increasingly important as new strategies are explored to reduce the risk of such complications.

PDB22

THE VALUE TO HIGH-RISK PATIENTS OF PREVENTING A CASE OF DIABETES

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OBJECTIVES: The objective of this study was to improve the design of diabetes risk-reduction interventions by quantifying high-risk patients' value of diabetes risks relative to the discomfort, inconvenience, and costs of diet, exercise, and weight-loss features of hypothetical diabetes-prevention programs. **METHODS:** A web-based, stated-choice survey instrument presented respondents with a sequence of choices among pairs of diabetes prevention program features and a "Neither" alternative. The instrument was pretested with a convenience sample of 16 subjects. The survey was administered to 400 subjects identified as high risk (obese, over age 45, 25% minorities) and to 200 subjects identified as lower risk (not obese, over age 45, 25% minorities). Each subject evaluated 9 choice tasks describing programs with varying levels of 7 features: diet, exercise, counseling, medication, weight loss, cost, and risk reduction. **RESULTS:** Discrete-choice patterns reveal the implicit relative importance of program features. More than half of the subjects evaluated diet, exercise, or counseling as more important than cost, medication, and weight-loss goal. However, cost proved to be important in actual stated choices among programs for over 85% of subjects. Over half of the subjects indicated they were willing to incur significant discomfort to reduce risks if the baseline diabetes risks were greater than 30%, which they are for high-risk individuals. Obese subjects were more likely to prefer interventions that included medication. **CONCLUSIONS:** There are significant cost-reduction benefits in avoiding the cost of glucose control and subsequent serious complications of diabetes patients. However, patient's adherence to a risk-reduction intervention depends on patients' perceived value of risk reduction relative to the of risk-reducing behavior. Patients are more likely to be adherent to risk-reduction programs with features that include effective diet and counseling features. Discrepancies between observed behavior and stated preferences for risk reduction may indicated poor perceptions of baseline risks and risk-reduction benefits.

PDB23

IS PSYCHOLOGICAL GENERAL WELL-BEING AN IMPORTANT PATIENT-REPORTED OUTCOME FOR THE EVALUATION OF DIABETES DRUG THERAPY?

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OBJECTIVE: Psychological general well-being is an important aspect of the quality of life of individuals with type-2 diabetes. The objective of this study was to determine the value of assessing psychological general well-being in diabetes drug therapy evaluations. **METHODS:** We administered the Psychological General Well-Being Schedule (PGWB) to 111 patients with type 2 diabetes (mean age = 55.8 years, 62% male, baseline A1c mean = 8.2%) participating in a Phase II randomized placebo-controlled trial of oral anti-diabetes treatment. The PGWB consists of 22 items divided into 6 subscales—anxiety, depressed